MAR 3 0 2009

510(k) Summary of Safety and Effectiveness
Emit® 2000 Sirolimus Assay
Emit® 2000 Siro / Tacro Sample Pretreatment Reagent
Emit® 2000 Sirolimus Calibrator

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K083487

1. Submitter's Contact Information and Date of Preparation

Submitter's Contact Information: Ms. Yuk-Ting Lewis
Siemens Healthcare Diagnostics Inc.
P.O. Box 6101, M/S 514
Newark, DE 19714
Attn: Yuk-Ting Lewis
Tel: 302-631-7626

Date of Preparation: Nov. 24, 2008

2. Proprietary Device Name / FDA Classification Name

Emit® 2000 Sirolimus Assay / Sirolimus Test System, 21 CFR 862.3840
Emit® 2000 Siro/Tacro Sample Pretreatment Reagent, 21 CFR 862.3840
Emit® 2000 Sirolimus Calibrator / Clinical Toxicology Calibrator, 21 CFR 862.3200

3. Identification of the Predicate Device

Abbott IMx® Sirolimus Assay, K042411
Abbott IMx® Sirolimus Calibrator, K042411

4. Device Description

The Emit® 2000 Sirolimus Assay is for in vitro diagnostic use for the quantitative analysis of sirolimus in human whole blood as an aid in the management of sirolimus therapy in kidney transplant patients. The Emit® 2000 Sirolimus Assay is comprised of an antibody reagent, a buffer reagent and an enzyme reagent. This assay contains mouse monoclonal antibodies with a high specificity for sirolimus.

The Emit® 2000 Siro/Tacro Sample Pretreatment Reagent is an accessory reagent for use with the Emit® 2000 Sirolimus Assay. The Emit® 2000 Siro/Tacro Sample Pretreatment Reagent is used to pretreat the whole blood samples, calibrators, and controls prior to testing with the Emit® 2000 Sirolimus Assay. The pretreatment process lyses the cells, extracts the sirolimus, and precipitates most of the blood proteins. The pretreated samples are centrifuged, and an aliquot of the resulting supernatant containing sirolimus is then assayed using the Emit® 2000 Sirolimus Assay.

The Emit® 2000 Sirolimus Calibrators are frozen material containing sirolimus in preserved whole blood hemolysate. There are six (6) calibrator levels containing 0, 3, 6, 12, 24 and 36 ng/mL.

5. Device Intended Use

The Emit® 2000 Sirolimus Assay is for the in vitro quantitative analysis of sirolimus in human whole blood as an aid in the management of sirolimus therapy in kidney transplant patients.

The Emit® 2000 Siro/Tac Sample Pretreatment Reagent is an accessory reagent for use with the Emit® 2000 Sirolimus Assay and/or the Emit® 2000 Tacrolimus Assay.

The Emit® 2000 Sirolimus Calibrators are intended for use in the calibration of the Emit® 2000 Sirolimus Assay.

6. Medical device to which equivalence is claimed and comparison information

The Emit® 2000 Sirolimus Assay is substantially equivalent in intended use and technological characteristics to the Abbott IMx® Sirolimus Assay. Both devices are immunoassays intended for use in the quantitative measurement of sirolimus in human whole blood. Both devices require a manual pretreatment. The Emit® 2000 Sirolimus Assay has an assay range of 3-30 ng/mL. The Abbott IMx Sirolimus Assay has an assay range of 0-30 ng/mL.

Comparison Information

Method comparison studies were conducted at two external sites comparing the Emit® 2000 Sirolimus Assay against LC/MS/MS. Samples from kidney transplant patients were used in the studies. The mean time since transplant was 6.9 years. The data from both sites were pooled, analyzed by linear regression and resulted in the following regression statistics.

Comparator	**Slope, ng/mL**	**Intercept**	**r**	**n**
LC/MS/MS	1.30	0.054	0.946	128

7. Conclusion

Based on a review of the devices technological features and the method comparison study, the Emit® 2000 Sirolimus Assay, Siro/Tacro Sample Pretreatment Reagent and Sirolimus Calibrators are substantially equivalent to the legally marked devices, the Abbott IMx® Sirolimus Assay and Sirolimus Calibrator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Siemens Healthcare Diagnostics Inc.
c/o Yuk-Ting Lewis
P.O. Box 6101, M/S 514
Newark, DE 19714

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Re: k083487
Trade name: EMIT 2000 Sirolimus Assay
Regulation Number: 21 CFR 862.3840
Regulation Name: Sirolimus Test System
Regulatory Class: Class II
Product Code: NRP, DLJ
Dated: February 26, 2009
Received: February 27, 2009

Dear Ms Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indication for Use

510(k) Number (if known):

Device Name: Emit® 2000 Sirolimus Assay
Emit® 2000 Siro/Tacro Sample Pretreatment Reagent
Emit® 2000 Sirolimus Calibrator

Indications For Use:

The Emit® 2000 Sirolimus Assay is for the in vitro quantitative analysis of sirolimus in human whole blood as an aid in the management of sirolimus therapy in kidney transplant patients.

The Emit® 2000 Siro/Tacro Sample Pretreatment Reagent is an accessory reagent for use with the Emit® 2000 Sirolimus Assay and/or the Emit® 2000 Tacrolimus Assay.

The Emit® 2000 Sirolimus Calibrators are intended for use in the calibration of the Emit® 2000 Sirolimus Assay.

Prescription Use ___x___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K083487